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EX

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,157	01/28/2004	Thomas P. Loughran JR.	USF-T190XC1	5993
23557	7590	08/01/2005	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			YAO, LEI	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,157	LOUGHREN ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 June 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,2 and 4-6 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-20-2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-6) in the reply filed on 6/27/05 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7-18 are cancelled. Claims 1-6 are pending. Claim 3 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claims 1-2 and 4-6 are examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/20/2004 is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

Claim Objections

Claim 1 is objected to for grammar error as "screening for". Amending the claim to "screening" would obviate this objective. Appropriate correction is required

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Smyth et al., (J Leukoc Biol., vol 57, page 88-93, Jan 1995).

Claim 1 is drawn to a method for screening, detecting, or diagnosing large granular lymphocyte leukemia in a person or animal, comprising obtaining a biological sample, and screening for upregulated or downregulated gene expression in LGL. Claim 2 is further drawn to claim 1, wherein the gene product is Granzymes.

Smyth et al., disclose a method of determining Large granular lymphocytes (LGLs) by detecting the expression of Granzyme B. Smyth et al., disclose result of the comparing gene expression between LGL and high-density small lymphocytes (HDLs; Page 89, column 1, line 1-10, page 91, figure 2, protein and page 92, figure 4, RNA).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warrington et al., (US Patent application publication, US2001/0044104, Pub date, Nov. 22, 2001) in view of Robertson et al., (Exp Hematol, vol 24, page 406-15, Feb, 1996) and Lamy et al., (Blood, Vol, 92, page 4771-4777, Dec, 1998).

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Claim 1 is set forth above. Claims 4-5 are further drawn to claim 1, wherein the expression of at least five gene products whose upregulation or downregulation. Claim 6 is further drawn to claim 1, wherein the sample is from peripheral blood.

Warrington et al., teach a method for screening, detecting or diagnosing a disease including acute lymphocytic leukemia using a gene expression profile obtained from microarray (paragraph 52, 54, and 95). Warrington et al., also teach differential expression of genes in a disease and normal tissue as an example (page 11-13). Warrington et al., also teach the advantages of comparing gene expression profiles between two sets of samples using microarray (paragraph 43, 44, and 45).

Warrington et al., do not teach that gene expression profile for large granular lymphocytes LGL leukemia.

Robertson et al., teach a method of characterizing cells derived from peripheral blood of a patient with CD3⁺ LGL leukemia and Robertson et al., also teach expression pattern of genes in the cells (page 410 figure 3 and 4).

Lamy et al., teach a characteristic of CD3⁺ LGL leukemia. Lamy et al., teach a gene expression by CD3⁺ LGL leukemia cells isolated from peripheral blood mononuclear cells derived from patients with CD3⁺ LGL leukemia (page 4773, figure 1 and table 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teaching of Warrington et al., on the general method of screening or diagnosing a disease using microarray and the teaching on the advantages of using the microarray method with the teaching of Robertson et al., and Lamy et al., on the characterizing LGL cells and detecting gene expression pattern of LGL leukemia cells. One of ordinary skill in the art would have been motivated to use the teachings of Warrington et al., Robertson et al., and Lamy et al., to measure the up and down gene expression profiles in LGL cells from LGL leukemia patients because Warrington et al., have shown a method of detecting gene expression profile by microarray and also suggest the advantages of comparing the gene expression profiles from microarray result, because Robertson et al., have shown a method of characterizing cells derived from peripheral blood of a patient with CD3⁺ LGL leukemia, and because Lamy et al., have shown a characteristic of CD3⁺ LGL leukemia by measuring a

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gene expression. One of skill in the art at the time of invention would have a reasonable expectation of success in screening, detecting, or diagnosing a of LGL leukemia by determining the up and down of regulation of gene expression in LGL cells from a patient with LGL leukemia.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

Karen A. Canella
KAREN A. CANELLA PH.D
PRIMARY EXAMINER